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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/725,845	12/02/2003	Tsong-Toh Yang	PD0706KQ2Q	3240

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SCHERING-PLOUGH CORPORATION
PATENT DEPARTMENT (K-6-1, 1990)
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EXAMINER	
SHEIKH, HUMERA N	

ART UNIT	PAPER NUMBER
1615	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/725,845	YANG, TSONG-TOH	
	Examiner	Art Unit	
	Humera N. Sheikh	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 April 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *64-94* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *64-94* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of the Application

Receipt of the Response after Non-Final Office Action, Applicant's Arguments/Remarks and the request for extension of time (3 months-granted), all filed 04/11/07 is acknowledged.

Claims 64-94 are pending in this action. No claims have been amended herein. Claims 1-63 have been previously cancelled. Claims 64-94 remain rejected.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321© or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 64-94 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-42 and 52-93 of U.S. Patent No. 6,495,167 B2

('167 Patent). Although the conflicting claims are not identical, they are not patentably distinct from each other because Patent '167 claims a dosage form comprising agglomerates of pharmacologically active agents, such as mometasone furoate. Patent '167 also claims a similar process of producing agglomerates that requires micronizing and agglomeration of mometasone furoate particles, similar to the instant '845 application.

With regard to the particular bulk density and particle sizes claimed, it is the position of the Examiner that suitable or effective bulk density and particle sizes could be determined by one of ordinary skill in the art through the use of routine or manipulative experimentation to obtain optimal results, as these are indeed variable parameters attainable within the art.

* * * * *

Claims 64-94 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-52 and 64-76 of U.S. Patent No. 6,503,537 B2 ('537 Patent). Although the conflicting claims are not identical, they are not patentably distinct from each other because Patent '537 claims a dosage form comprising agglomerates of pharmacologically active agents, such as mometasone furoate. Patent '537 also claims a similar process of producing agglomerates that requires micronizing and agglomeration of mometasone furoate particles, similar to the instant '845 application.

With regard to the particular bulk density and particle sizes claimed, it is the position of the Examiner that suitable or effective bulk density and particle sizes could be determined by one of ordinary skill in the art through the use of routine or manipulative experimentation to obtain optimal results, as these are indeed variable parameters attainable within the art.

* * * * *

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 64-94 are rejected under 35 U.S.C. 103(a) as being unpatentable over Trofast (U.S. Pat. No. 6,371,171 B1) in view of Sequeira *et al.* (U.S. Pat. No. 5,837,699) OR Briggner *et al.* (U.S. Pat. No. 5,874,063).

The instant invention is drawn to a uniform dry powder composition comprising agglomerates of fine particles of one pharmacologically active agent which is mometasone furoate and particles of lactose wherein the composition has a bulk density of from about 0.29 to about 0.38 g/cm^3, and wherein the composition is substantially homogeneous.

The instant invention is also drawn to a process for preparing a uniform dry powder composition comprising agglomerates of fine particles of one pharmacologically active agent which is mometasone furoate and particles of lactose wherein the composition has a bulk density of from 0.29 to 0.38 g/cm^3 and the composition is substantially homogeneous, the process comprising:

(a) micronizing particles of mometasone furoate and particles of lactose, so that at least one of the mometasone furoate and the lactose has a preselected amount of convertible amorphous content which is capable of being converted to crystalline form upon exposure to a

preselected stimulus, the convertible amorphous content being provided in an amount which is sufficient to allow for the formation of agglomerates;

(b) agglomerating the particles of mometasone furoate and lactose while maintaining the preselected amount of convertible amorphous content; and

(c) exposing the convertible amorphous content within the agglomerates to the preselected stimulus to convert the convertible amorphous content to a crystalline form.

Trofast ('171) teaches dry powdered medicaments comprising fine agglomerates of terbutaline, budesonide and lactose, wherein the composition has a bulk density of from about 0.2 to 0.4 g/ml and a particle size of less than about 10 microns (see reference column 1, line 60 through col. 2, line 15).

Trofast also teaches a process of treating a finely divided powder that includes forcing the powder through a sieve to form agglomerates, and spheronizing the agglomerates. According to Trofast, this process has been found to produce agglomerates having excellent handling properties, which have sufficient strength to withstand packaging and storage, but which are sufficiently soft in order to break down easily into primary particles when they are expelled from an inhaler during inhalation therapy (col. 1, line 60 through col. 2, line 6).

The example at col. 5, line 45, demonstrates a process of agglomeration, whereby spheronized agglomerated particles resulted from micronized lactose.

Regarding the bulk density, it would appear that the ranges taught by Trofast (0.2-0.4 g/ml) fall within the applicant's claimed ranges (about 0.29 to about 0.38 g/cm^3), although the prior art uses a different unit of measurement for the bulk density.

Trofast does not teach the instant steroid drug, mometasone furoate.

Sequeira et al. **('699)** teach dry powder compositions comprising particles of mometasone furoate for treating corticosteroid-responsive diseases, wherein the anhydrous mometasone furoate is admixed with a dry excipient - dry lactose (see reference column 2, line 20 through col. 3, line 29); (col. 7, lines 18-35) and abstract.

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use the dry powder mometasone fuorate composition of Sequeira *et al.* within the composition of Trofast because Sequeira explicitly teach that mometasone furoate exhibits superior anti-inflammatory effects in treating airway passage diseases, such as asthma and allergic rhinitis by acting on surfaces of the upper and lower airways passages and lungs while having substantially minimum systemic effects. The expected result would be an improved mometasone furoate dry powder composition for the treatment of respiratory diseases.

As discussed above, Trofast teaches dry powdered medicaments comprising fine agglomerates of terbutaline, budesonide and lactose, wherein the composition has a bulk density of from about 0.2 to 0.4 g/ml and a particle size of less than about 10 microns (see reference column 1, line 60 through col. 2, line 15).

Trofast does not teach the instant steroid drug, mometasone furoate.

Briggner et al. **('063)** teach a powder pharmaceutical formulation comprising finely divided particles of mometasone furoate in combination with excipients – lactose wherein the

formulation is used in the treatment of asthma and other related inflammatory diseases of the lung (see reference column 1, line 31 through col. 3, line 67).

Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made to use the powder mometasone fuorate composition of Briggner within the composition of Trofast because Briggner teaches a composition for the treatment of asthma and other inflammatory diseases of the lung, wherein anti-asthmatic drugs include suitable and effective steroids, such as mometasone furoate. The expected result would be an improved mometasone furoate dry powder composition for the treatment of respiratory and inflammatory diseases.

The instant claims are drawn to a uniform dry powder composition comprising mometasone furoate with lactose wherein the composition has a bulk density of from about 0.29 to about 0.38 g/cm^3. The prior art teaches dry powder compositions comprising steroid drugs, mometasone furoate, terbutaline and budesonide with lactose, wherein the composition of Trofast comprises finely divided particles having a bulk density of from 0.2 to 0.4 g/ml. There are no unexpected results, which accrue from the instant bulk density claimed, since the prior art teaches a similar bulk density range. Furthermore, it is deemed obvious to one of ordinary skill in the pharmaceutical art that suitable ranges of bulk density could be determined through routine or manipulative experimentation as these are indeed variable parameters attainable within the art.

Thus, given the teachings of the prior art delineated above, the instant invention, when taken as a whole, would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Pertinent Art

Prior Art made of record and considered relevant by the examiner:

U.S. Pat. No. 5,637,620 TROFAST et al. 06-1997

Response to Arguments

Applicant's arguments filed 04/11/07 have been fully considered but they are not persuasive.

- **Non-Statutory Double Patenting Rejection**:

Applicant argued, "Claims 64-94 are rejected based on the ground of non-statutory obviousness-type double patenting as being unpatentable in view of US6495167 and 6503537. Applicants traverse these rejections. Applicants submit that Terminal Disclaimers will be submitted upon an indication of allowance."

Applicant's arguments have been considered. Examiner acknowledges Applicant's notification to submit Terminal Disclaimers upon indication of allowable subject matter. The non-statutory obviousness-type double patenting rejections have been maintained herein.

- **35 U.S.C. §103(a) Rejection of claims 64-94 over Trofast (6,371,171) in view of Sequiera (5,837,699) or Briggner (5,874,063)**:

Applicant argued, "Applicants submit that the teachings of the combined references do not teach a composition that is substantially homogeneous as presently claimed. As such, Applicants respectfully submit that the Action fails to prove a case of obviousness and withdrawal of the rejections is warranted."

Applicant's arguments have been considered but were not persuasive. The argument that "the combined references do not teach a composition that is substantially homogeneous" was not persuasive since the Trofast reference explicitly teaches that 'in solid-solid mixing, one of the most important features is to *ensure content uniformity*'. Trofast teaches that a remicronization step after the conditioning step of the fine powder with low energy is advantageous. The step is carried out using enough energy to break down powder agglomerates but not with so much energy that the size of the particles is themselves affected. Trofast states that "such a step gives a composition wherein the active substance and the carrier substance are *substantially uniformly distributed*, having for example, a relative standard deviation of less than 3% (preferably less than 1%) and does not disturb the crystallinity of the particles (see column 3, lines 5-18). The Examples at columns 3-4 of Trofast further demonstrates obtaining evenly distributed mixtures of active ingredient and carrier (i.e., lactose). Thus, the prior art explicitly teaches and obtains a substantially uniform or homogeneous composition, as also desired by Applicant. The prior art obtains similar compositions as claimed, with the use of similar components formulated for the same field of endeavor as that claimed by Applicant.

Hence, given the teachings of the prior art discussed above, the instant invention, when taken as a whole, would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

--No claims are allowed at this time.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Humera N. Sheikh whose telephone number is (571) 272-0604. The examiner can normally be reached on Monday through Friday from 8:00A.M. to 5:30P.M., alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have any questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Humera N. Sheikh

Primary Examiner

Art Unit 1615

June 25, 2007

HUMERA N SHEIKH
PRIMARY EXAMINER
Tc-1600

hns